UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

5/2/2019

SUBJECT: Acute Toxicity Review for *Organipeel*™, EPA Reg. No.: 92708-R

FROM: Lindsay O'Dell
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Jenny Tao, Team Leader (Acute Toxicology) 04/30/2019
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline Hardy, PM Team 34 / Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Registrant: Apeel Sciences		
Decision No.: 547400	Submission No.: 1029216	E-Sub No.: 35138
DP No.: 450703	Action Code: A540	
MRID No(s).: 50748205-50748210		

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
021801	77-92-9	Citric acid	0.66%
		Other Ingredients	99.34%
		Total	100%

I. BACKGROUND

The Registrant, Apeel Sciences, has submitted an application for pesticide registration for their product: *Organipeel*™, EPA Reg. No. 92708-R. The Registrant has submitted six acute toxicity studies (MRIDs 50748205-50748210) to fulfill the acute oral, dermal, inhalation, primary eye and skin irritation and skin sensitization data requirements. The test substance used in each study was identified as EI05.3, which the Registrant has validated that is the experimental name. This end use product is added to water then applied to produce to reduce spoilage and decay caused by non-public health microorganisms.

II. FINDINGS/RECOMMENDATIONS

1. Acute Oral Toxicity

The results of the study (MRID 50748205) showed no deaths at a limit dose of 5000 mg/kg for 3 female rats, thus the LD_{50} is >5000 mg/kg. The study is acceptable, and the product is placed in Toxicity Category IV.

2. Acute Dermal Toxicity

The results of the study (MRID 50748206) showed no deaths at a limit dose of 5000 mg/kg for 5 female rat and 5 male rats, thus the LD_{50} is >5000 mg/kg. The study is acceptable, and the product is placed in Toxicity Category IV.

3. Acute Inhalation Toxicity

The results of the study (MRID 50748207) showed no deaths at a mean gravimetric concentration of 5.11 mg/kg for 5 female rat and 5 male rats, thus the LC_{50} is >5.11 mg/kg. The study is acceptable, and the product is placed in Toxicity Category IV.

4. Primary Eye Irritation

The results of the study (MRID 50748208) demonstrated that all animals were free of ocular irritation by day 4. This study is acceptable, and the product is placed in Toxicity Category III.

5. Primary Skin Irritation

The results of the study (MRID 50748209) demonstrated that one of three female rabbits exhibited slight erythema at 72 hours. This study is acceptable, and the product is placed in Toxicity Category IV.

6. Dermal Sensitization

The results of the study (MRID 50748210) indicated that the proposed product is a non-sensitizer.

7. The acute toxicity profile of *Organipeel*™, EPA Reg. No. 92708-R, is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	50748205	IV	Acceptable
Acute Dermal Toxicity	50748206	IV	Acceptable
Acute Inhalation Toxicity	50748207	IV	Acceptable
Primary Eye Irritation	50748208	III	Acceptable
Primary Skin Irritation	50748209	IV	Acceptable
Dermal Sensitization	50748210	Nonsensitizer	Acceptable

III. CONCLUSION

The data submitted satisfy the acute toxicity data requirements to support the registration of the proposed product, *Organipeel*™, EPA Reg. No. 92708-R.

IV. PRODUCT LABELING

1. Signal Word: "CAUTION"

2. The statement, "Keep Out of Reach of Children (KOROC)", is required. It should appear immediately above the front-panel signal word "CAUTION".

3. The Agency's Label Review Manual, (https://www.epa.gov/pesticide-registration/label-review-manual), suggests the following human-hazard precautionary statements:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

> CAUTION: Causes moderate eye irritation. Avoid contact with eyes and clothing. Wear protective eye wear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID:

> IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OCSPP 870.1100)

Product Manager: J. Hardy/PM 34 **Reviewer:** L. O'Dell

MRID No.: 50748205 **Study Completion Date:** 11/26/2018

Study No.: 48818

Testing Laboratory: Product Safety Labs, Dayton, NJ.

Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: E105.3

Dose levels: 5000 mg/kg bw

Animals: Rat, Sprague-Dawley

Number/Sex: 3 Females

Age: 9-11 weeks

Weight: 189-196 grams

Source: SAGE Labs

Method: OCSPP 870.1100; OECD 425

Summary:

1. **Estimated LD_{50}:** >5000 mg/kg bw
2. **Toxicity Category:** IV
3. **Classification:** Acceptable

Deviations from protocol: None.

Results:

Gavage administration of the test material diluted 30% w/w in distilled water was given to three fasted animals as provided in Table 1. An initial limit dose of 5,000 mg/kg was administered to one rat by oral gavage. Due to the absence of mortality in this rat, two additional rats received the same dose level. Since these animals survived, no additional animals were tested. Following administration, one rat exhibited a reduced fecal volume. However, this animal recovered by Day 2 and, along with the remaining animals, appeared

active and healthy for the remainder of the 14-day observation period. No gross abnormalities were noted when the animals were necropsied at the conclusion of the study.

Table 1. Reported Mortality – Limit Test			
Dosing Sequence	**Dose Level (mg/kg bw)**	**Short-Term Outcome**	**Long-Term Outcome**
1	5000	O	O
2	5000	O	O
3	5000	O	O

O = Survival; X = Death

.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OCSPP 870.1200)

Product Manager: J. Hardy/PM 34 **Reviewer:** L. O'Dell

MRID No.: 50748206 **Study Completion Date:** 11/26/2018

Study No.: 48819

Testing Laboratory: Product Safety Labs, Dayton, NJ.

Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: E105.3

Dose levels: 5000 mg/kg bw

Animals: Rat, Sprague-Dawley

Number/Sex: 5 Males and 5 females

Age: 10-11 weeks

Weight: Males: 318-338 grams; Females: 204 - 223 grams

Source: SAGE Labs

Summary:

1. **Estimated LD_{50}:** >5000 mg/kg bw
2. **Toxicity Category:** IV
3. **Classification:** Acceptable

Deviations from Guideline 870.1200:

None.

Results:

Five thousand milligrams of test substance per kilogram of body weight was applied as a dry paste (65% w/w mixture in distilled water) for a 24-hour dermal exposure to previously clipped skin (2 × 3 in. application site for all rats; about 10% of the total body surface area) (Table 1). All animals survived test substance administration, gained body weight, and appeared active and healthy during the study. There were no signs of gross toxicity, dermal irritation, adverse clinical effects, or abnormal behavior. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period. Under the conditions of this study, the single dose acute dermal LD_{50} of the test substance is >5000 mg/kg bw in male and female rats.

Table 1. Mortality			
Nominal dose (mg/kg bw)	**Number Dead / Number Tested**		
	Males	**Females**	**Combined**
5000	0 / 5	0 / 5	0 / 10

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OCSPP 870.1300)

Product Manager: J. Hardy/PM 34 **Reviewer:** L. O'Dell

MRID No.: 50748207 **Study Completion Date:** 11/26/2018

Study No.: 48820

Testing Laboratory: Product Safety Labs, Dayton, NJ.

Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: E105.3

Concentrations: Chamber (gravimetrically determined): 5.11 mg/L

Nominal: 8.15 mg/L.

Chamber Type: Nose-only

Animals: Rat, Sprague-Dawley-derived

Sex: 5 Males and 5 Females

Age: 10-11 weeks at exposure

Weight: Males: 296-348 g; Females: 201 - 224 g

Source: SAGE® Labs

Method: OCSPP 870.1300; OECD 403

Summary:

1. **LC_{50}:** Males: >5.11 mg/L
   Females: >5.11 mg/L
2. **Mean MMAD:** 3.77 µm (GSD = 2.74)
3. **Toxicity Category:** IV
4. **Classification:** Acceptable

Deviations from Guideline 870.1300: Individual body weight was to be recorded initially, on Days 1, 3, and approximately weekly thereafter. However, the Day 3 body weights were not completed for all animals.

Results:

The table below gives the mortality following a four-hour nose-only inhalation exposure to a mean gravimetric concentration of 5.11 mg/L of the test substance after it was ground in a ball mill for 28 hours prior to aerosolization. All animals survived exposure to the test atmosphere and gained weight during the study. Following exposure, one rat exhibited ano-genital staining. However, this animal recovered by Day 7 and, along with the remaining animals, appeared active and healthy for the remainder of the 14-day observation period. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the study.

Reported Mortality

Exposure Concentration (mg/L)	Number dead / Number tested		
	Males	Females	Combined
5.11	0 / 5	0 / 5	0 / 10

Chamber Atmosphere

Mean (±SD) Exposure Conc. (mg/L)	Mean MMAD (µm)	Mean GSD	% of Particles < 3.3 µm
5.11 ± 0.27 (Range: 4.83–5.45)	3.77 (3.76, 3.77)	2.74 (2.80, 2.68)	35.8 (36.4, 35.3)

Chamber Environment

Exposure Level (mg/L)	5.11
Chamber Volume (L)	28
Total Airflow Rate (Lpm)	86
Temperature (°C)	21-23
Relative Humidity (%)	30-36

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OCSPP 870.2400)

Product Manager: J. Hardy/PM 34 **Reviewer:** L. O'Dell

MRID No.: 50748208 **Study Completion Date:** 11/26/2018

Study No.: 48821

Testing Laboratory: Product Safety Labs, Dayton, NJ.

Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: E105.3

Dosage: 0.1 mL

Animals: Rabbit, New Zealand albino strain

Sex: 3 Females

Age: 11 weeks

Weight: 2039-2222g

Source: Robinson Services Inc.

Summary:

1. **Toxicity Category**: III
2. **Classification**: Acceptable

Deviations from Guideline 870.2400 and other comments: None noted.

Results:

The tables below provide the results ("positive" irritation and mean total irritation scores) following instillation of 0.1 mL (0.1 mg/kg bw) of the undiluted test material into the right eye of three rabbits. Prior to instillation both the treated and control eyes of each animal were topically anesthetized with 0.5% Tetracaine Hydrochloride Ophthalmic Solution, and the animals were also given buprenorphine (0.1 mg/kg) prior to treatment and at appropriate intervals thereafter. All animals appeared active and healthy and gained body weight during the study. Apart from the eye irritation noted below, there were no other signs of gross toxicity, adverse clinical effects, or abnormal behavior. One hour after test substance instillation, two treated eyes exhibited 'positive' conjunctivitis and one treated eye exhibited minimal conjunctivitis. There was no corneal opacity or iritis observed in any treated eye during the

study. The overall incidence and severity of irritation decreased gradually with time. Positive irritation cleared from both treated eyes by 48 hours. All animals were free of ocular irritation by Day 4 (study termination). The Maximum Mean Total Score was 9.3 at one hour. Under the conditions of this study, the test substance was classified as mildly irritating to the eye.

Incidence of Irritation

Time Post-Instillation	No. of Animals Testing "Positive" / No. of Animals Tested			
	Corneal Opacity	Iritis	Conjunctiva [a]	
			Redness	Chemosis
1 hour	0 / 3	0 / 3	1 / 3	1 / 3
24 hours	0 / 3	0 / 3	0 / 3	1 / 3
48 hours	0 / 3	0 / 3	0 / 3	0 / 3
72 hours	0 / 3	0 / 3	0 / 3	0 / 3
4 days	0 / 3	0 / 3	0 / 3	0 / 3

[a] Redness or chemosis score of 1 not considered a "positive score" according to EPA 870.2400.

Severity of Irritation

Time Post Instillation	Mean Total Score [a]
1 hour	9.3
24 hours	5.3
48 hours	1.3
72 hours	0.7
4 days	0.0

[a] Draize method of scoring (1944).

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OCSPP 870.2500)

Product Manager: J. Hardy/PM 34 **Reviewer:** L. O'Dell

MRID No.: 50748209 **Study Completion Date:** 11/27/2018

Study No.: 48822

Testing Laboratory: Product Safety Labs, Dayton, NJ.

Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: E105.3

Dosage: 0.5 mL

Animals: Rabbit, New Zealand albino strain

Sex: 3 Females

Age: 15 weeks

Weight: 2494-2575g

Source: Robinson Services Inc.

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Deviations from Guideline 870.2500: None noted.

Results:

The table below provides the individual Draize scores from four-hour dermal exposures of three female rabbits to 0.5 mL of the moistened test material applied to intact clipped application sites measuring 6 cm^2. Within 30-60 minutes of patch removal, all three treated sites exhibited very slight erythema. There was no edema observed at any treated site during the study. The overall incidence and severity of irritation decreased gradually with time. All animals were free of dermal irritation by Day 7 (study termination). The Primary Dermal Irritation Index (PDII) calculated for this test substance was 0.5, and the test material was a slight irritant (US EPA, 1988).

Individual Dermal Irritation Scores following the four-hour exposure

Animal No.	Sex	Erythema / Edema			
		Time After Patch Removal			
		60 minutes	24 hours	48 hours	72 hours
3501	F	1 / 0	0 / 0	0 / 0	0 / 0
3502	F	1 / 0	1 / 0	1 / 0	1 / 0
3503	F	1 / 0	0 / 0	0 / 0	0 / 0

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (OCSPP 870.2600)

Product Manager: J. Hardy/PM 34 **Reviewer:** L. O'Dell

MRID No.: 50748210 **Study Completion Date:** 11/26/2018

Study No.: 48823

Testing Laboratory: Product Safety Labs, Dayton, NJ.

Author: Carolyn Lowe, LATG

Quality Assurance (40 CFR §160): Included

Test Material: E105.3

Positive Control Material: alpha-Hexylcinnamaldehyde (HCA; ≥95%), undiluted

Species: Guinea pigs/Hartley albino,

Number/Sex: 34 Males (20 test animals, 10 naïve controls, 4 used in irritation screen)

Weight: 325-398 g (test and naïve control groups)

Age: Young adult

Source: Elm Hill Breeding Labs

Method: Buehler method; Twenty test animals were treated with a 60% w/w mixture of the test substance in mineral oil (induction) and challenged with a 60% w/w mixture of the test substance in mineral oil. Ten naïve control animals were treated with a 60% w/w mixture of the test substance in mineral oil at the challenge application of the test group. Concentrations were selected based on preliminary irritation testing.

Summary:

1. E105.3 was not a sensitizer under the conditions of this study.

2. Classification: Acceptable

Deviations from Guideline 870.2600: None

Results:

There was no dermal irritation observed at any test site during the induction or challenge phases. The results of the historical positive control study (conducted within six months of the current study) were appropriate. It was concluded that E105.3 was not a sensitizer.

Animal Group	Dose Preparation	Number of Animals	Incidence of positives
Test animals	60% w/w mixture in mineral oil	20	0/20
Naive controls	60% w/w mixture in mineral oil	10	0/10
Positive Control (historical)	Alpha-hexylcinnamaldehyde (≥95%)	5	2/5

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
92708	Jacqueline Hardy	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Organipeel™	34	

5. Name and Address of Applicant *(Include ZIP Code)*

Apeel Technology, Inc. (DBA Apeel Sciences)
71 S. Los Carneros Road
Goleta, CA 93117

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. N/A

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Apeel Sciences is submitting this application for registration of Organipeel™ as a new end-use antimicrobial pesticide product. The PRIA Category is A540 and the PRIA fee of $5,107.00 has been paid. Please see payment receipt which accompanies the cover letter of this application. Payment Tracking ID: 26DPDH59.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [X] Paper [ ] Other (Specify) _____
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	1.1 oz (30 g), 2.2 lbs (1 kg), or 22 lbs (10 kg)	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [X] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

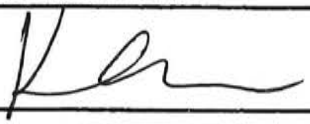
1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Katie Davis	Senior Regulatory Manager	1-805-203-0146 x7090

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
	Senior Regulatory Manager
4. Typed Name	**5. Date**
Katie Davis	12/14/2018

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

Print Form

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
92708-1	Jacqueline Hardy	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Organipeel	34	

5. Name and Address of Applicant *(Include ZIP Code)*

Apeel Technology, Inc. (DBA Apeel Sciences)
71 South Los Carneros Road
Goleta, CA 93117

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. N/A

Product Name N/A

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Addition of Alternate Source of Inert Ingredient per PR Notice 98-10

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Katie Davis	Director, Regulatory Affairs	(805) 203-0146 ext. 7090

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Kara D	Director, Regulatory Affairs
4. Typed Name	**5. Date**
Katie Davis	2021/03/16

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Apeel Sciences, 71 S. Los Carneros Road, Goleta, CA 93117 1-805-203-0146	92708-
Active Ingredient(s) and/or representative test compound(s)	**Date**
Citric acid	December 13, 2018
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	**Product Name**
Indoor-Food	Organipeel™

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

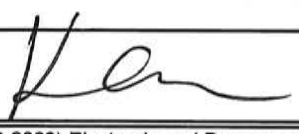
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	12/14/2018	Katie Davis, Senior Regulatory Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Ave, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX – Generic Matrix

Date December 14, 2018	EPA Reg. No./File Symbol 92708-	Page 1 of 4
Applicant's/Registrant's Name & Address: Apeel Sciences, 71 S. Los Carneros Rd., Goleta, CA 93117	Product Organipeel™	

Ingredient(s): Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY DATA REQUIREMENTS					
870.1100	Acute Oral Toxicity	Waiver Request			See Footnote 1
870.1200	Acute Dermal Toxicity	"			"
870.1300	Acute Inhalation Toxicity	"			"
870.2400	Primary Eye Irritation	"			"
870.2500	Primary Dermal Irritation	"			"
870.2600	Skin Sensitization	"			"
870.3100	90-Day Oral Toxicity (rat)	"			"
970.3150	90-Day Oral (nonrodent)	"			"
870.3200	21-Day Dermal Toxicity	"			"
870.3250	90-Day Dermal Toxicity	"			"
870.3465	90-Day Inhalation Toxicity	"			"
870.6200	90-Day Neurotoxicity	"			"
870.3700	Developmental Toxicity Study	"			"
870.3800	Reproduction and Fertility Effects	"			"
870.4100	Chronic Oral (rodent)	"			"
870.4200	Carcinogenicity (2 rodent species)	"			"
870.4300	Combined Chronic/Oncogenicity	"			"
870.5100	Reverse Mutation Assay	"			"
870.5300	*In-vitro* Mammalian Gene Mutation	"			"
870.5395	*In Vivo* cytogenetics	"			"
870.7485	General Metabolism	"			"
870.7800	Immunotoxicity	"			"

Signature	Name and Title:	Date
	Katie Davis, Senior Regulatory Manager	12/14/2018

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DATA MATRIX – Generic Matrix

Date December 14, 2018	EPA Reg. No./File Symbol 92708-	Page 2 of 4
Applicant's/Registrant's Name & Address: Apeel Sciences, 71 S. Los Carneros Rd., Goleta, CA 93117	Product Organipeel™	

Ingredient(s): Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
NON-TARGET ORGANISM DATA REQUIREMENTS					
850.2100	Acute Avian Oral	Waiver Request			See Footnote 2
850.1010	Aquatic Freshwater Invertebrate Toxicity (*dapnia magna*)	"			"
850.1075	Acute Freshwater Fish toxicity (bluegill sunfish and rainbow trout)	"			"
870.1300	Fish Early-Life Stage	"			"
870.1400	Aquatic Invertebrate Life-Cycle	"			"
850.4400	Aquatic Plant Growth – Vascular Plants	"			"
850.5400	Aquatic Plant Growth - Algae	"			"
ENVIRONMENTAL FATE DATA REQUIRMENTS					
835.1110	Activated Sludge Sorption Isotherm	Waiver Request			See Footnote 3
835.2120	Hydrolysis	"			"
835.2240	Photodegradation in Water	"			"
835.4100	Aerobic Soil Metabolism	"			"
835.4200	Anaerobic Soil Metabolism	"			"
835.4300	Aerobic Aquatic Metabolism	"			"
835.4400	Anaerobic Aquatic Metabolism	"			"
835.1240	Leaching/Adsorption/Desorption	"			"
850.6800	Activated Sludge Respiration Inhibition Test	"			"

Signature	**Name and Title:**	**Date**
	Katie Davis, Senior Regulatory Manager	12/14/2018

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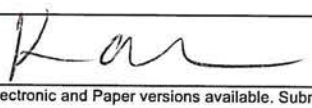
DATA MATRIX – Generic Matrix

Date December 14, 2018	EPA Reg. No./File Symbol 92708-	Page 3 of 4
Applicant's/Registrant's Name & Address: Apeel Sciences, 71 S. Los Carneros Rd., Goleta, CA 93117	Product Organipeel™	

Ingredient(s): Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Occupation and Residential Exposure Data Requirements					
875.1200	Dermal Exposure – Indoor	Waiver Request			See Footnote 4
875.1400	Inhalation Exposure – Indoor	"			"
875.1600	Data Reporting and Calculations	"			"
875.1700	Product Use Information	"			"
875.2400	Dermal Exposure – Post Application	"			"
875.2500	Inhalation Exposure – Post Application	"			"
875.2800	Description of Human Activity	"			"
RESIDUE CHEMISTRY					
860.1100	Chemical Identity	See CSF			
860.1200	Directions for Use	See Product Label			
860.1300	Nature of the Residue In Plants	Waiver Request			See Footnote 5
860.1340	Residue Analytical Methods	"			"
860.1500	Crop Field Trials	"			"
					"

NOTES (cont.)

Signature	Name and Title:	Date
	Katie Davis, Senior Regulatory Manager	12/14/2018

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DATA MATRIX – Generic Matrix

Date December 14, 2018	EPA Reg. No./File Symbol 92708-	Page 4 of 4
Applicant's/Registrant's Name & Address: Apeel Sciences, 71 S. Los Carneros Rd., Goleta, CA 93117	Product Organipeel™	

Ingredient(s): Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

1. According to the *Registration Eligibility Decision (RED)* document for citric acid the Registration Review evaluations, all generic toxicology data requirements have been waived. See attachment.
2. According to the *Registration Eligibility Decision (RED)* document for citric acid the Registration Review evaluations, all generic non-target organism (ecological effects) data requirements have been waived. See attachment.
3. According to the *Registration Eligibility Decision (RED)* document for citric acid the Registration Review evaluations, all generic environmental fate data requirements have been waived. See attachment.
4. According to the *Registration Eligibility Decision (RED)* document for citric acid the Registration Review evaluations, all generic occupational and residential exposure data requirements have been waived. See attachment.
5. According to the *Registration Eligibility Decision (RED)* document for citric acid the Registration Review evaluations, all generic residue chemistry data requirements have been waived. See attachment.

Signature	Name and Title:	Date
Kar	Katie Davis, Senior Regulatory Manager	12/14/2018

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DATA MATRIX

Date 05/24/2019	EPA Reg No./File Symbol 92708-	Page 1 of 2
Applicant's/Registrant's Name & Address Apeel Sciences, 71 S. Los Carneros Rd., Goleta, CA 93117	Product Organipeel™	

Ingredient Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	507482-01	Apeel Sciences	OWN	Sub. 05/24/2019
830.1600	Description of Materials Used to Produce the Product	507482-01	Apeel Sciences	OWN	Sub. 05/24/2019
830.1620	Description of Production Process	507482-01	Apeel Sciences	OWN	Sub. 05/24/2019
830.1650	Description of Formulation Process	507482-01	Apeel Sciences	OWN	Sub. 05/24/2019
830.1670	Discussion of Formation of Impurities	507482-01	Apeel Sciences	OWN	Sub. 05/24/2019
830.1700	Preliminary Analysis	507482-01	Apeel Sciences	OWN	Sub. 05/24/2019
830.1750	Certified Limits	507482-01	Apeel Sciences	OWN	Sub. 05/24/2019
830.1800	Enforcement Analytical Method	507482-04	Apeel Sciences	OWN	Sub. 05/24/2019
830.6302	Color	507482-02	Apeel Sciences	OWN	Sub. 05/24/2019
830.6303	Physical State	507482-02	Apeel Sciences	OWN	Sub. 05/24/2019
830.6304	Odor	507482-02	Apeel Sciences	OWN	Sub. 05/24/2019
830.7000	pH	507482-02	Apeel Sciences	OWN	Sub. 05/24/2019
830.7300	Density/Relative Density/Bulk Density	507482-02	Apeel Sciences	OWN	Sub. 05/24/2019
830.6317	Storage Stability	507482-03	Apeel Sciences	OWN	Sub. 05/24/2019
830.6320	Corrosion Characteristics	507482-03	Apeel Sciences	OWN	Sub. 05/24/2019

Signature	Name and Title	Date
	Katie Davis, Senior Regulatory Manager	05/24/2019

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DATA MATRIX

Date 05/24/2019	EPA Reg No./File Symbol 92708-	Page2 of 2
Applicant's/Registrant's Name & Address Apeel Sciences, 71 S. Los Carneros Rd., Goleta, CA 93117	Product Organipeel™	

Ingredient Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1800	Enforcement Analytical Method	507482-04	Apeel Sciences	OWN	Sub. 05/24/2019
870.1100	Acute Oral Toxicity	507482-05	Apeel Sciences	OWN	Sub. 05/24/2019
870.1200	Acute Dermal Toxicity	507482-06	Apeel Sciences	OWN	Sub. 05/24/2019
870.1300	Acute Inhalation Study	507482-07	Apeel Sciences	OWN	Sub. 05/24/2019
870.2400	Primary Eye Irritation	507482-08	Apeel Sciences	OWN	Sub. 05/24/2019
870.2500	Primary Skin Irritation	507482-09	Apeel Sciences	OWN	Sub. 05/24/2019
870.2600	Dermal Sensitization Test	507482-10	Apeel Sciences	OWN	Sub. 05/24/2019

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DATA MATRIX

Date 12/14/2018	EPA Reg No./File Symbol 92708-	Page 1 of 2
Applicant's/Registrant's Name & Address Apeel Sciences, 71 S. Los Carneros Rd., Goleta, CA 93117	Product Organipeel™	

Ingredient Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition		Apeel Sciences	OWN	Sub. 12/14/2018
830.1600	Description of Materials Used to Produce the Product		Apeel Sciences	OWN	Sub. 12/14/2018
830.1620	Description of Production Process		Apeel Sciences	OWN	Sub. 12/14/2018
830.1650	Description of Formulation Process		Apeel Sciences	OWN	Sub. 12/14/2018
830.1670	Discussion of Formation of Impurities		Apeel Sciences	OWN	Sub. 12/14/2018
830.1700	Preliminary Analysis		Apeel Sciences	OWN	Sub. 12/14/2018
830.1750	Certified Limits		Apeel Sciences	OWN	Sub. 12/14/2018
830.1800	Enforcement Analytical Method		Apeel Sciences	OWN	Sub. 12/14/2018
830.6302	Color		Apeel Sciences	OWN	Sub. 12/14/2018
830.6303	Physical State		Apeel Sciences	OWN	Sub. 12/14/2018
830.6304	Odor		Apeel Sciences	OWN	Sub. 12/14/2018
830.7000	pH		Apeel Sciences	OWN	Sub. 12/14/2018
830.7300	Density/Relative Density/Bulk Density		Apeel Sciences	OWN	Sub. 12/14/2018
830.6317	Storage Stability		Apeel Sciences	OWN	Sub. 12/14/2018
830.6320	Corrosion Characteristics		Apeel Sciences	OWN	Sub. 12/14/2018

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	Katie Davis, Senior Regulatory Manager	12/14/2018

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DATA MATRIX

Date 12/14/2018	EPA Reg No./File Symbol 92708-	Page2 of 2
Applicant's/Registrant's Name & Address Apeel Sciences, 71 S. Los Carneros Rd., Goleta, CA 93117	Product Organipeel™	

Ingredient Citric Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1800	Enforcement Analytical Method		Apeel Sciences	OWN	Sub. 12/14/2018
870.1100	Acute Oral Toxicity		Apeel Sciences	OWN	Sub. 12/14/2018
870.1200	Acute Dermal Toxicity		Apeel Sciences	OWN	Sub. 12/14/2018
870.1300	Acute Inhalation Study	Text	Apeel Sciences	OWN	Sub. 12/14/2018
870.2400	Primary Eye Irritation		Apeel Sciences	OWN	Sub. 12/14/2018
870.2500	Primary Skin Irritation		Apeel Sciences	OWN	Sub. 12/14/2018
870.2600	Dermal Sensitization Test		Apeel Sciences	OWN	Sub. 12/14/2018

Signature	Name and Title	Date
	Katie Davis, Senior Regulatory Manager	12/14/2018

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SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)

1. PRODUCT NAME: Organipeel™		**2. Reg. No.** 92708-
3. COMPANY NAME: Apeel Sciences		**4. SUBMISSION DATE:** 12/14/2018
5. FIRST SUBMISSION [X] **6. RESUBMISSION** [ ]	**7. PESTICIDE TYPE:** Antimicrobial	**10. REGISTRATION** [X]
8. FORMULATED MANUFACTURING-USE PRODUCT [ ] **or 9. END-USE PRODUCT** [X]		**11. REREGISTRATION** [ ]
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN): Jacqueline Hardy, PM 34		**12. REREG CASE #**

14. GUIDELINE REFERENCE NO.(GRN)/TITLE	15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES	16. MRID or REPORT NO.
Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)		
-6302 Color	White.	48817
-6303 Physical State	Solid powder.	48817
-6304 Odor	Practically odorless.	48817
-6314 Oxidation/Reduction: Chemical Incompatibility	Not applicable.	Not applicable.
-6315 Flammability/Flame Extension	Not applicable.	Not applicable.
-6316 Explodability	Not applicable.	Not applicable.
-6317 Storage Stability	Stable. Retains level of active ingredient when stored at 54C for 14 days.	48817
-6319 Miscibility	Not applicable.	Not applicable.
-6320 Corrosion Characteristics	No corrosion of the storage container was observed.	48817
-6321 Dielectric Breakdown Voltage	Not applicable.	Not applicable.
-7000 pH	8.44	48817
-7100 Viscosity	Not applicable.	Not applicable.
-7300 Density/Relative Density/ Bulk Density	Pour density: 0.5; Tap density: 0.6.	48817

EPA Form 8570-36 (07/JAN/1998)

INSTRUCTIONS ON HOW TO COMPLETE THE SUMMARY FORM (PR NOTICE 98-1)

1, 3 to 6 & 8 to 13: Self-explanatory.

2: Cite Registration Number or File Symbol Number. Leave blank if unknown or cite company number followed by a hyphen and XXX.

7: State whether your product is an insecticide, herbicide, fungicide, rodenticide, plant growth regulator, etc.

14: OPPTS Test Guidelines, Series 830, Product Properties (EPA publication 712-C-96-310,8/96) supersedes the Pesticide Assessment Guidelines, Subdivision-D, Product Chemistry, Series 60 to 64, and serves as one guideline for national and international product chemistry data requirements for chemical pesticides. Consistent with the certification statement, applicants must conduct the studies in substantial conformity with the detailed procedures described in OPPTS Test Guidelines. Published procedures or modifications may be used but must be referenced. If the applicant/registrant is fulfilling product chemistry requirements for a biochemical or microbial pesticides, cite the requirements opposite the corresponding GRNs listed on the form for chemical pesticides.

15: Indicate the experimental value, its average deviation and, where applicable, the method used, e.g., GC, HPLC, DTA/DSC (differential thermal analysis/scanning colorimetry). Provide qualitative descriptions, where applicable, and references such as ASTM, CIPAC, OECD, Federal Register, CFR, CRC Publication, Official Journal of the European Communities, EPA's Guidelines, etc. Examples on how to report some of these properties are shown on Attachment 3. Non-applicable studies can be indicated by using the term "N/A or Not-Applicable" then citing a regulatory and/or scientific reason as per the footnotes to the Table in 40 CFR 158.190. Studies in progress can be indicated as such "I/P or In Progress." Values or qualitative description of referenced or shared studies should also be indicated on the Form. All boxes in the form must be completed with data summaries and appropriate terms if not applicable or in progress. Resubmissions can be completed using a new form citing the applicants's response to the specific data gap or deficiencies and filling the remaining boxes with "N/A or Not-Applicable" if previously submitted and found adequate or "Upgraded" if a submitted study was rejected and needed upgrading, then cite the date of preceding data submissions followed by a summary of the upgraded information. The Form is expandable to allow reporting the requirements for registration/reregistration on separate sheets identified by product's name and Reg. No./File Symbol or Company No. Please note that abbreviations may be used if explained by identifying the corresponding full terms as footnotes to the Form.

16: Indicate company Report number if the study was generated and retained by the applicant or MRID number (Master Record Identification Number) if the study was previously submitted and assigned a number by the EPA. Company report number should not exceed eighteen (18) characters. It will be used by the Agency to recall certain studies if needed. When received by the Agency, properly formatted data will be assigned MRID number(s).

Specific Instructions by Guideline Reference Number (GRN)

GRNs 830-6319, -6321, -7000, -7100 & -7300 should be conducted in compliance with OPPTS Test Guidelines Series 830 Product Properties, or reported at 25°C unless otherwise noted.

GRN 830-6302, -6303 & -6317: Report qualitative description where applicable as per PR Notice 92-5.

GRN's 830-6315, -7000 & -7300: Reported values on the form should be consistent with those given on the Confidential Statement of Formula (CSF).

GRN 830-6303: Provide a brief description, e.g., solid, granular, liquid, powder, aqueous solution, emulsion, volatile liquid, gas, etc.

GRN 830-6314: Not applicable if the product does not contain an oxidizing or reducing agent or functional group of significant reactivity. This requirement includes those substances which the product is likely to contact including the storage container and dispensers during handling and use, e.g., iron, aluminum.

GRN 830-6315 For organic liquids, provide flash point in degrees Celsius (with Fahrenheit in parentheses). For aerosols provide flame extension and/or flash back if applicable to the nearest centimeters (with inches in parentheses). For non-combustible liquids and solids state "Non-Applicable."

GRN 830-6316: Indicate method of determination and cite references, e.g., differential thermal analysis/scanning colorimetry (DTA/DSC), (sharp exotherm at 60 degrees Celsius), by shock or impact explodability, hammer test or by structural analog, contains several nitro groups as in picric acid.
GRN 830-6317: Should be conducted for a minimum of one year under ambient warehouse conditions using commercial containers. Report the type of containers used and any changes in product composition at intervals of three months to the end of the test period relative to that at the beginning of testing. Any physical changes at the end of the test period must also be reported. Data on the stability study for technical grade of active ingredients (GRN 830-6313) will not satisfy the requirements for the storage stability (GRN 830-6317) for qualifying products. An interim 30 days storage stability study can be included with the first submission requesting a conditional registration pending compliance with all the requirements.

GRN 830-6320: May be conducted simultaneously with GRN 830-6317. Indicate changes in the commercial packaging containers (fluorinated high density polyethylene, plastic film, polyethylene liners, steel, tin, or paper) over a minimum of one year in storage under warehouse conditions.

GRN 830-7100: Flow curves for non-Newtonian fluids on viscosity can be appended to the form.

GRN 830-7300: For solids or powders, provide the bulk density in units, e.g., g/cc or lb/ft^3 whichever is preferred. For liquids, provide the density in grams/ml or lbs/gal.

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SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)

1. PRODUCT NAME: Organipeel™		**2. Reg. No.** 92708-
3. COMPANY NAME: Apeel Sciences		**4. SUBMISSION DATE:** 05/24/2019
5. FIRST SUBMISSION ☒ **6. RESUBMISSION** ☐	**7. PESTICIDE TYPE:** Antimicrobial	**10. REGISTRATION** [☒
8. FORMULATED MANUFACTURING-USE PRODUCT [☐ **or 9. END-USE PRODUCT** [☒		**11. REREGISTRATION** [☐
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN): Jacqueline Hardy, PM 34		**12. REREG CASE #**

14. GUIDELINE REFERENCE NO.(GRN)/TITLE	15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES	16. MRID or REPORT NO.
Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)		
-6302 Color	White.	48817
-6303 Physical State	Solid powder.	48817
-6304 Odor	Practically odorless.	48817
-6314 Oxidation/Reduction: Chemical Incompatibility	Not applicable - Product does not contain oxidizing or reducing agents.	Not applicable.
-6315 Flammability/Flame Extension	Not applicable - Product is not composed of flammable materials.	Not applicable.
-6316 Explodability	Not applicable - Product is not composed of explodable materials.	Not applicable.
-6317 Storage Stability	Stable. Retains level of active ingredient when stored at 54C for 14 days.	48817
-6319 Miscibility	Not applicable - Product is a solid powder.	Not applicable.
-6320 Corrosion Characteristics	No corrosion of the storage container was observed.	48817
-6321 Dielectric Breakdown Voltage	Not applicable - Not intended for use in or around electrical equipment.	Not applicable.
-7000 pH	8.44	48817
-7100 Viscosity	Not applicable - Product is a solid powder.	Not applicable.
-7300 Density/Relative Density/ Bulk Density	Pour density: 0.5; Tap density: 0.6.	48817

EPA Form 8570-36 (07/JAN/1998)

INSTRUCTIONS ON HOW TO COMPLETE THE SUMMARY FORM (PR NOTICE 98-1)

1, 3 to 6 & 8 to 13: Self-explanatory.

2: Cite Registration Number or File Symbol Number. Leave blank if unknown or cite company number followed by a hyphen and XXX.

7: State whether your product is an insecticide, herbicide, fungicide, rodenticide, plant growth regulator, etc.

14: OPPTS Test Guidelines, Series 830, Product Properties (EPA publication 712-C-96-310,8/96) supersedes the Pesticide Assessment Guidelines, Subdivision-D, Product Chemistry, Series 60 to 64, and serves as one guideline for national and international product chemistry data requirements for chemical pesticides. Consistent with the certification statement, applicants must conduct the studies in substantial conformity with the detailed procedures described in OPPTS Test Guidelines. Published procedures or modifications may be used but must be referenced. If the applicant/registrant is fulfilling product chemistry requirements for a biochemical or microbial pesticides, cite the requirements opposite the corresponding GRNs listed on the form for chemical pesticides.

15: Indicate the experimental value, its average deviation and, where applicable, the method used, e.g., GC, HPLC, DTA/DSC (differential thermal analysis/scanning colorimetry). Provide qualitative descriptions, where applicable, and references such as ASTM, CIPAC, OECD, Federal Register, CFR, CRC Publication, Official Journal of the European Communities, EPA's Guidelines, etc. Examples on how to report some of these properties are shown on Attachment 3. Non-applicable studies can be indicated by using the term "N/A or Not-Applicable" then citing a regulatory and/or scientific reason as per the footnotes to the Table in 40 CFR 158.190. Studies in progress can be indicated as such "I/P or In Progress." Values or qualitative description of referenced or shared studies should also be indicated on the Form. All boxes in the form must be completed with data summaries and appropriate terms if not applicable or in progress. Resubmissions can be completed using a new form citing the applicants's response to the specific data gap or deficiencies and filling the remaining boxes with "N/A or Not-Applicable" if previously submitted and found adequate or "Upgraded" if a submitted study was rejected and needed upgrading, then cite the date of preceding data submissions followed by a summary of the upgraded information. The Form is expandable to allow reporting the requirements for registration/reregistration on separate sheets identified by product's name and Reg. No./File Symbol or Company No. Please note that abbreviations may be used if explained by identifying the corresponding full terms as footnotes to the Form.

16: Indicate company Report number if the study was generated and retained by the applicant or MRID number (Master Record Identification Number) if the study was previously submitted and assigned a number by the EPA. Company report number should not exceed eighteen (18) characters. It will be used by the Agency to recall certain studies if needed. When received by the Agency, properly formatted data will be assigned MRID number(s).

Specific Instructions by Guideline Reference Number (GRN)

GRNs 830-6319, -6321, -7000, -7100 & -7300 should be conducted in compliance with OPPTS Test Guidelines Series 830 Product Properties, or reported at 25°C unless otherwise noted.

GRN 830-6302, -6303 & -6317: Report qualitative description where applicable as per PR Notice 92-5.

GRN's 830-6315, -7000 & -7300: Reported values on the form should be consistent with those given on the Confidential Statement of Formula (CSF).

GRN 830-6303: Provide a brief description, e.g., solid, granular, liquid, powder, aqueous solution, emulsion, volatile liquid, gas, etc.

GRN 830-6314: Not applicable if the product does not contain an oxidizing or reducing agent or functional group of significant reactivity. This requirement includes those substances which the product is likely to contact including the storage container and dispensers during handling and use, e.g., iron, aluminum.

GRN 830-6315 For organic liquids, provide flash point in degrees Celsius (with Fahrenheit in parentheses). For aerosols provide flame extension and/or flash back if applicable to the nearest centimeters (with inches in parentheses). For non-combustible liquids and solids state "Non-Applicable."

GRN 830-6316: Indicate method of determination and cite references, e.g., differential thermal analysis/scanning colorimetry (DTA/DSC), (sharp exotherm at 60 degrees Celsius), by shock or impact explodability, hammer test or by structural analog, contains several nitro groups as in picric acid.
GRN 830-6317: Should be conducted for a minimum of one year under ambient warehouse conditions using commercial containers. Report the type of containers used and any changes in product composition at intervals of three months to the end of the test period relative to that at the beginning of testing. Any physical changes at the end of the test period must also be reported. Data on the stability study for technical grade of active ingredients (GRN 830-6313) will not satisfy the requirements for the storage stability (GRN 830-6317) for qualifying products. An interim 30 days storage stability study can be included with the first submission requesting a conditional registration pending compliance with all the requirements.

GRN 830-6320: May be conducted simultaneously with GRN 830-6317. Indicate changes in the commercial packaging containers (fluorinated high density polyethylene, plastic film, polyethylene liners, steel, tin, or paper) over a minimum of one year in storage under warehouse conditions.

GRN 830-7100: Flow curves for non-Newtonian fluids on viscosity can be appended to the form.

GRN 830-7300: For solids or powders, provide the bulk density in units, e.g., g/cc or lb/ft^3 whichever is preferred. For liquids, provide the density in grams/ml or lbs/gal.

Form Approved OMB No. 2070-0060

March 16, 2021

Jacqueline Hardy, Product Manager (34)
U.S. Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Subject: Notification of Addition of Source of Inert Ingredient per PR Notice 98-10

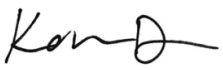
Ms. Hardy,

Apeel Sciences is submitting the enclosed documents per PR Notice 98-10 to notify the Agency of the addition of an alternate source of an inert ingredient in Organipeel (EPA Reg. No. 92708-1).

Please note that the alternate source of inert ingredient may be marketed under one of two product codes, as seen in the enclosed ingredient data sheets. Both product codes represent ingredients produced to identical specifications.

Please do not hesitate to contact me with any questions.

Thank you,



Katie Davis
Director, Regulatory Affairs
(805) 203-0146 ext. 7090
katie.davis@apeelsciences.com

Enclosures:

- EPA Form 8570-1 (1 pg)
- EPA Form 8570-4, two copies (2 pgs) – CONFIDENTIAL
- Ingredient data sheets (4 pgs) – CONFIDENTIAL

Apeel Sciences
71 S. Los Carneros Road
Goleta, CA 93117

December 14, 2018

Jacqueline Hardy, Product Manager (34)
Regulatory Management Branch No. 2
Antimicrobials Division (7510P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Registration Application for New End-Use Product
Registrant: Apeel Sciences, Company Number 92708
Product Name: Organipeel™
Active Ingredient: Citric Acid

Dear Ms. Hardy,

Apeel Technology, Inc. (DBA Apeel Sciences) is submitting the enclosed application for a FIFRA Section 3 registration of Organipeel™ (File Symbol 92708-) as a new end-use antimicrobial pesticide product. Organipeel™ is intended to provide a reduction of spoilage and decay caused by non-public health microorganisms on the surface of unprocessed fruits and vegetables and is comprised entirely of food-grade, edible components. As you might recall, Apeel Sciences met with the EPA Antimicrobials Division (AD) on August 14, 2018 to discuss the registration application for Organipeel™, including AD expectations for data requirements. The minutes from this meeting are attached. The enclosed application was developed based on the outcome from this consultation.

The following documents are included with this application:

- Cover letter
- Meeting Minutes from August 14, 2018 meeting with AD
- Transmittal Document for Organipeel™
- EPA Form 8570 -1 Application for Pesticide Registration of Organipeel™
- EPA Form 8570-4 Confidential Statement of Formula for Organipeel™
- EPA Form 8570-34 Certification with Respect to Citation of Data for Organipeel™
- EPA Form 8570-35 Data Matrix for Organipeel™
- EPA Form 8570-36 Summary of the Physical and Chemical Properties of Organipeel™
- Draft Product Label for Organipeel™
- Data Volumes 1-10 characterizing the end-use product Organipeel™

Regarding the food-use status of the Organipeel™ components, please note that per 40CFR §180.950 citric acid is exempt from the requirement of a tolerance when used on all food crops. The inert ingredients in Organipeel™ are also exempt from the requirement of a tolerance per 40 CFR §180.910, when used pre- or post-harvest on all food crops (see the Confidential Appendix of the Product Chemistry submission for more information on the inert ingredients).

To support the product specific data requirements for Organipeel™, Apeel is submitting product chemistry and acute toxicology data. As noted above, no public-health claims are included on the product label for Organipeel™ so the submission of efficacy data is not required. Since Apeel is using an unregistered source of citric acid to formulate Organipeel™, chemistry data on this source is being provided in the product chemistry study. Apeel is relying on the "cite-all" method to satisfy all other generic data requirements for citric acid.

The PRIA Category has been identified as A540 and the PRIA fee of $5,107.00 has been paid. Please see payment receipt which accompanies the cover letter of this application. Payment Tracking ID: 26DPDH59.

Should you have any questions or if we can support your review in any way, please do not hesitate to contact me at (805) 203-0146 extension 7090, or via email at katie.davis@apeelsciences.com.

Sincerely,

Katie Davis
Senior Regulatory Manager
Apeel Sciences

Pay.gov

Receipt

Tracking Information

Pay.gov Tracking ID: 26DPDH59

Agency Tracking ID: 75625162149

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: $5,107.00

Transaction Date: 11/28/2018 04:21:56 PM EST

Payment Date: 11/28/2018

Registration Number:

Company Name: Apeel Sciences

Company Number: 92708

Action Code: A540

Account Information

Cardholder Name: Shelly Garduno

Card Type: Visa

Card Number: **********0215

Apeel Sciences
71 S. Los Carneros Road
Goleta, CA 93117

December 24, 2019

Lorena Rivas, Registration Risk Manager
Regulatory Management Branch No. 2
Antimicrobials Division (7510P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Response to Deficiencies Found During Review of Application
Registrant: Apeel Sciences, Company Number 92708
Product Name: Organipeel™
File Symbol: 92708-R

Dear Ms. Rivas,

Please find enclosed updated documents to respond to deficiencies communicated to Apeel Sciences from EPA's review of Apeel Sciences' application for registration for the new end use product, Organipeel™.

The following documents are included with this submission:

- Cover letter
- EPA Form 8570-4 Confidential Statement of Formula for Organipeel™
- EPA Form 8570-35 Data Matrix for Organipeel™
- EPA Form 8570-36 Summary of the Physical and Chemical Properties of Organipeel™
- Red Line Version Product Label for Organipeel™
- Clean Product Label for Organipeel™

Should you have any questions or if we can support your review further, please do not hesitate to contact me at (805) 203-0146 extension 7090, or via email at katie.davis@apeelsciences.com.

Sincerely,

Katie Davis
Senior Regulatory Manager
Apeel Sciences

Apeel Sciences
71 S. Los Carneros Rd.
Goleta, CA 93117

August 15, 2018

Jacqueline Hardy
U.S. Environmental Protection Agency
Antimicrobials Division (7510P), Team 34
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Meeting Notes: Apeel Sciences – EPA Antimicrobials Division Pre-Application Meeting Regarding Organipeel™

Dear Ms. Hardy,

Apeel Sciences would like to thank members of the Antimicrobials Division for their time and participation in a pre-application review of Apeel Sciences' registration plans for the new end-use antimicrobial pesticide, Organipeel™, held on August 14, 2018.

As a follow-up to this meeting, Apeel Sciences has drafted the enclosed meeting notes which provide a summary of the discussion and actions taken during the meeting. In addition to the meeting notes, Apeel Sciences is providing the following documents for your reference:

1. Draft Product Label, Version 1: Providing an update to the original draft label submitted by Apeel Sciences to update the word 'organisms' to 'microorganisms'.
2. Draft Product Label, Version 2: Providing a version of the product label that contains additional language regarding the status of Organipeel™ as an allowed input for organic production.
3. Organic Materials Review Institute (OMRI) certificate for Organipeel™. The OMRI certificate demonstrates that Organipeel™ is OMRI Listed for use in certified organic production or food processing and handling according to the USDA National Organic Program.

Should you have any questions, please do not hesitate to contact me at (805) 203-0146 extension 0790, or via email at kathryn.davis@apeelsciences.com. Please let us know if you have any additional feedback on these materials.

Sincerely,

Kathryn Davis
Senior Regulatory Manager
Apeel Sciences

EPA Antimicrobials Division – Apeel Sciences
Pre-Application Meeting Regarding Organipeel™
August 14, 2018

Attendees

EPA Antimicrobials Division (AD): Jacqueline Hardy, Lorena Rivas, Lindsay Odell, Karen Hicks
Apeel Sciences (Apeel): Jenny Du, Katie Davis, Erik Petersen, Eliot Harrison

Meeting Notes

- Jenny Du delivered a presentation on behalf of Apeel, providing an introduction to Apeel and background information on the subject of the pre-application meeting, Organipeel™.
- EPA clarified that Apeel will need to submit product chemistry data on the Technical Grade Active Ingredient (TGAI); however, this data may be submitted via cross-reference to existing sources (RED Document, EPA interim decision on citric acid, MERCK Index, etc.). EPA noted the MERCK Index is likely the best source for this information. Additionally, the data matrix submitted with the application will need to cite this information. EPA commented that occupational and ecological data will not be required for the application.
- EPA clarified that Apeel's active ingredient is an unregistered source of citric acid; and therefore, 5 Certificates of Analysis (COA's) from the supplier will need to be provided with Apeel's application.
- EPA referenced a list of commonly consumed products and noted that if citric acid is on that list, it may help justify exemption from some standard data requirements.
    - **ACTION: EPA to provide or confirm if citric acid is on the commonly consumed products list.**
- EPA noted that the typical 'six-pack' of toxicology studies is normally required for all new end-use antimicrobial pesticides; however, Apeel may pursue a few options to potentially gain exemption from this requirement:
    - (1) Technical argument submitted for pre-evaluation: The pre-evaluation will be Apeel's technical argument (known as a bridging argument) for why toxicology data should not be required on the end-use product. The bridging argument would be based on existing safety data for the individual components. There is a formal PRIA category for this action, minimal cost, and 90-day review period.
        - **ACTION: EPA to confirm PRIA category for the pre-evaluation, as they are considering using BPPD's PRIA category in the future and are unsure of the category number off-hand.**
    - (2) Data waiver request: Apeel may submit a formal data waiver request. The request must focus on why it is not possible to conduct the particular studies on the end-use product.
- EPA noted that Apeel may choose to conduct toxicology studies as a back-up plan in the event that EPA does not accept Apeel's pre-evaluation bridging argument.
- EPA noted that current PPE requirements on the label are driven by the toxicology endpoints for the TGAI; however, citric acid is not known to have toxicology endpoints. Therefore, the current PPE requirements may be overly stringent.

- Apeel confirmed that if Apeel was to elect to conduct toxicology studies, and no endpoints were returned in the final results, that the PPE requirements may be reduced.
- EPA noted that there has been some internal (within AD) discussion regarding the product name, Organipeel™, and the possibility that the name could be considered "false or misleading".
- Apeel clarified that the name is in reference to the fact that Organipeel™ is OMRI Listed as an allowed input for organic production and post-harvest handling.
- Apeel offered that it may be useful for Apeel to include the OMRI symbol or other clarifying language indicating that the product is permitted for use in organic crop production on the product label.
- **ACTION: EPA to confirm if it is possible for Apeel to include the OMRI symbol and/or language indicating the product's permitted use in organic production on the Organipeel™ product label, which would make the name acceptable.**
- EPA suggested that this issue could be shared and discussed during the 'label claims meeting', which occurs every Thursday.
- **ACTION: Apeel agreed to this approach and will provide an updated product label as well as the Organipeel™ OMRI certificate prior to Thursday 8/16 for AD to review during the upcoming 'label claims meeting'.**
- EPA agreed with Apeel's understanding that the best PRIA category is A540.
    - **ACTION: Apeel will file Organipeel™ Section-3 application for registration under the A540 PRIA category.**
- EPA asked whether Apeel intends to include any graphics on the final product label. Apeel confirmed that if anything is added, it will most likely be the Apeel Sciences company logo.
- EPA asked how Apeel is currently marketing its products and if Apeel has intentions to sell directly to the end consumer. Apeel confirmed that the current marketing approach is focused upstream in the supply chain (e.g., growers, packers, distributers) and may consider direct sale to consumers in the future.
- **ACTION: Apeel to draft meeting notes and submit to EPA via email following the meeting.**

Jacqueline Hardy, Product Manager (34)
Antimicrobials Division (7510P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Subject: Submission of one copy of the revised final printed label per the Notice of Registration for Organipeel™ (EPA Reg. No. 92708-1), dated 6/7/19

Dear Ms. Hardy,

On behalf of Apeel Technology, Inc. (DBA Apeel Sciences), the attached EPA Form 8570-1 has been completed to account for the following regarding Organipeel™ (EPA Reg. No. 92708-1):

> *Submission of one copy of the revised final printed label per the Notice of Registration for Organipeel™ (EPA Reg. No. 92708-1) dated 6/7/19.*

The EPA's direction in the Notice of Registration stipulates that one copy of the revised final printed label for Organipeel™ (EPA Reg. No. 92708-1) be submitted. As three package sizes appear as options on Organipeel™'s Master Label, one copy of the revised final printed label for each package size has been included in this submission, for a total of three unique labels.

Please do not hesitate to reach out should you have any questions.

Sincerely,

DocuSigned by:
Katie Davis
5B97D1C8F65444A...

2020-03-06

Katie Davis
Associate Director, Regulatory Affairs
katie.davis@apeelsciences.com
1-805-203-0146 x7090

Attached: EPA Form 8570-1 (one total), Revised final printed labels for each package size (three total)

Print Form

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
92708-1	Jacqueline Hardy	☒ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Organipeel™	34	

5. Name and Address of Applicant *(Include ZIP Code)*

Apeel Technology, Inc. (DBA Apeel Sciences)
71 South Los Carneros Road
Goleta, CA 93117

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. N/A

Product Name N/A

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☒ Final printed labels in response to Agency letter dated 6/7/19
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of one copy of the revised final printed label per the Notice of Registration for Organipeel™ (EPA Reg. No. 92708-1) dated 6/7/19.

See attachment for further information.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Katie Davis	Associate Director, Regulatory Affairs	1-805-203-0146 x7090

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
DocuSigned by: Katie Davis 5B97D1C8F65444A...	Associate Director, Regulatory Affairs
4. Typed Name	**5. Date**
Katie Davis	2020-03-05

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S.Environmental Protection Agency,1200 Pennsylvania Ave, NW,Washington, DC20460.**

INSTRUCTIONS: This form is to be used all applications for new registration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-34)**.** [If not exempted by 40 CFR 152.81(b)(4)].
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Data Matrix.

Submission of Labeling -Labeling should first be submitted in the form of draft labeling with all applications. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 **x** 11 inch file**.** Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data -Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I**,** II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - The section must be completed, as applicable, for all registration actions.

1. **Company /Product Number -** Insert your company number, if one has been assigned by EPA. This number rnay have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager -**If known, fill in the name end PM number of the EPA Product Manager.
3. **Proposed Classification -**Specify the proposed classification of this product. For most products the classification would be "None".
4. **Product Name -**Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant -**The name of the firm or parson and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in theUnited Statesmust have an authorized agent residing in theUnited Statesto act for them in all registration matters. The name rand complete mailing address of such an agent must accompany this application.
6. **Expedited Review -**FlFRA section 3 (c) 3 **(B)** provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II -This section must be completed for a11 applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. Subject of submission -Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for he submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by…"; "reregistration submission"; "general label revision of direction for use", `notification for…". Attach a separate page if additional space is needed.

SECTION III - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging -**Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container**- Indicate type of container in which product will be marketed.
3. **Location of Net Contents -**Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container -**Specify the net contents of all retail containers for your product.
5. **Location of Use Directions -**Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product -**Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) -This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5.Self-explanatory
6. EPA Use Only